Congress of the United States
Washington, DC 20515

March 29, 2012

The Honorable Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Building 1, Room 2217
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As members of the House Energy and Commerce Committee, we write to express our concerns regarding the Food and Drug Administration's (FDA) draft guidance for industry entitled, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," which was published on July 5, 2011.

We believe that regulations should provide useful clarity to the regulated industry, allow innovation and market forces to prevail, and, above all, remain grounded in the statutory authority provided by Congress to the regulators. The draft guidance on new dietary ingredients falls short on these criteria.

Congress included language in the Food Safety Modernization Act directing FDA to clarify when a dietary supplement ingredient is a new dietary supplement ingredient, intending that any FDA guidance would conform to the Dietary Supplement Health and Education Act (DSHEA) of 1994. However, the draft guidance released by FDA in July of 2011 appears to undermine DSHEA in a number of critical respects. Therefore, we respectfully request FDA to reexamine and significantly rework this guidance so it does not undermine consumer access to safe, affordable dietary supplement products.

We understand that with this guidance, FDA may in effect be establishing a pre-market review process for dietary supplements and impose standards that were deemed suitable for food additives. Furthermore, it appears that this guidance will require multiple filings on the same ingredient in certain situations which is at odds with the statute, past rulemaking and longstanding practice. Given FDA's current workload, it does not seem prudent to follow this course of action. Imposing these regulatory requirements on products that have a long history of safe use will increase costs on manufacturers at a time when we should be encouraging, rather than hindering their efforts.

We recognize that this issue has been difficult for industry and FDA to resolve. Nonetheless, Congress expects and the industry needs FDA to develop a reasonable guidance document on this matter. It is our hope that FDA will engage in meaningful dialogue with the

relevant stakeholders in industry to bring forward a useful guidance on New Dietary Ingredient submissions that is consistent with the DSHEA.

Sincerely,

BRETT GUTHRIE
Member of Congress

JOE BARTON
Member of Congress

JOHN SHIMKUS
Member of Congress

ED WHITFIELD
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MARY BONO MACK
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